UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,375	09/24/2001	Ikunoshin Kato	KATO18	8012

1444 7590 07/06/2005

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,375	KATO ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,42 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5-0-0

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/2005 has been entered. Claims 8, 42 and 43 are currently pending in the application and are addressed herein.

Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asada et al. (EP 0 870 839 A1) in view of Asada et al. (Journal of Biochemistry, 1998; Vol. 123, pages 1041-1047) and further in view of Kubota et al. (Journal of Dermatological Science, 1996; Vol. 12, pages 36-43) and Qin et al. (Journal of Clinical Immunology, 1993; Vol. 13, No. 2, pages 152-161).

The instant claims are drawn to a composition for transfecting a cell at a site at a site of vascularization in vivo comprising (1) a retrovirus that contains a gene to be transfected, (2) CH-296, and (3) human umbilical vein endothelial (HUVEC) cells; wherein the gene to be transected encodes a therapeutic protein such as an enzyme or cytokine.

It is noted that the limitations, "an effective amount for transfecting a cell at a site of vascularization in vivo" do appear to be defined in the specification. As such, given the broadest reasonable interpretation of the claims consistent with the specification, the limitation "an effective amount for transfecting a cell at a site of vascularization in vivo" is interpreted as encompassing any amount.

Asada et al. (EP 0 870 839 A1) teaches a method for introducing a gene into a target cell using a composition comprising (1) a retrovirus, (2) a cell, and (3) a functional material having (i) a retrovirus binding domain, and (ii) a target cell binding domain (e.g., see abstract; page 5 lines 35-41). Asada et al. (EP 0 870 839 A1) specifically teaches that the functional material having affinity for the retrovirus and target cell can be CH-296 (e.g., see page 24, lines 40-55). Asada et al. (EP 0 870 839 A1) also teaches that the retrovirus can comprise a gene encoding an

enzyme (e.g., see p. 6, lines 41-45), and that the target cell can be any one of a number of different cells, including angio-endothelial cells (e.g., see page 5, lines 46-53). Therefore, Asada et al. (EP 0 870 839 A1) teaches a composition comprising (1) a retrovirus, (2) CH-296, and (3) an angio-endothelial cell wherein the retrovirus encodes a therapeutic protein that is an enzyme. It is noted that Asada et al. (EP 0 870 839 A1) teaches that the functional material having affinity for the target cell can be used to target a retrovirus to a cell that expresses the VLA-4 or VLA-5 antigen (e.g., see page 4, lines 21-24; page 8, lines 42-55; page 12, lines 43-47; page 6, lines 10-12; etc.).

Asada et al. (EP 0 870 839 A1) does not explicitly teach that CH-296 binds to VLA-4 or that the cells are human umbilical vein cord (HUVEC) cells.

However, Asada et al. (1998) teaches that CH-296 is a recombinant polypeptide comprising a CS1 site which is recognized by VLA-4. Asada et al. (1998) also specifically teaches that CH-296 can enhance gene transfer through binding to both retrovirus particles and target cells that express integrins VLA-5 and/or VLA-4 (e.g., see abstract; and page 1041, second column, last paragraph).

Kubota teaches that human umbilical vein endothelial cord (HUVEC) cells express the CDw49d antigen. It is noted that Kubota does not explicitly indicate that the CDw49d antigen is very late antigen-4 (VLA-4); however, Qin teaches that CDw49d is very late antigen-4 (VLA-4) (e.g., see abstract; page 153, first column end of first full paragraph; page 155, under "Expression of Adhesion Molecules"; etc.).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Asada et al. (EP 0 870 839 A1), Asada

et al. (1998), Kubota and Qin to create a composition comprising a retrovirus that expresses an enzyme, CH-296, and an angio-endothelial cell (as taught by Asada) wherein the angio-endothelial cell is a human umbilical vein endothelial cord (HUVEC) cell (as taught by Kubota and Beekhuizen), with a reasonable expectation of success.

One of ordinary skill in the art would have been motivated to make the claimed composition in view of the teachings that (1) the CH-296 can be used to enhance transfection of VLA-4 angio-endothelial cells with a retrovirus encoding an enzyme, and (2) HUVEC cells are angio-endothial cells that express VLA-4/CDw49d antigen.

Response to Arguments

Applicant's arguments, see pages 4-5 of the communication filed 2/25/2005, with respect to the rejection(s)of claim(s) 8, 42 and 43 under 35 USC 112,1st and 2nd paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made for the reasons indicated herein.

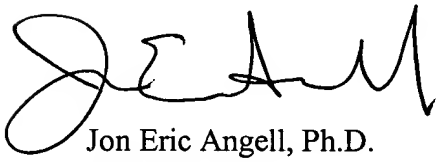
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon Eric Angell, Ph.D.
Art Unit 1635